

specific embodiments where are disclosed herein and still obtain a like or similar result without departing from the spirit and scope of the invention. All of the compositions and methods disclosed and claimed herein can be made and executed without undue experimentation in light of the present disclosure. It will be apparent that certain compounds which are both physiologically and chemically related may be substituted for the therapeutic compound described herein while the same or similar results are achieved.

We claim:

1. An improved multi-layered osmotic device for the controlled delivery of one or more active agents to one or more environments of use wherein the osmotic device comprises:

a) a compressed core comprising a first active agent and an osmotic agent for controlled and continuous release of the drug first active agent

b) a semipermeable membrane surrounding the core and having a preformed passageway therein, said membrane being permeable to a fluid in the environment of use and substantially impermeable to the first active agent;

c) an inert, completely erodible water soluble polymer coat comprising poly(vinylpyrrolidone)-(vinyl acetate) copolymer partially or substantially completely surrounding the semipermeable membrane and plugging the passageway in the wall; and

d) an external coat comprising a second active agent for immediate release of the drug wherein the first active agent is released from the core after the polymer coat has partially or completely dissolved or eroded, and the first and second active agents are released into the same or different environments of use to provide a controlled delivery of the one or more active agents.

2. An osmotic device according to claim 1 wherein the compressed core further comprises poly(vinylpyrrolidone).

3. An osmotic device according to claim 1 wherein the semipermeable membrane consists essentially of cellulose acetate and poly(ethylene glycol).

4. An osmotic device according to claim 1 wherein the external coat comprises poly(vinylpyrrolidone) and poly(ethylene glycol).

5. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent.

6. An osmotic device according to claim 1 wherein the first active agent in the core comprises a therapeutic agent.

7. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a therapeutic agent.

8. An osmotic device according to claim 7 wherein the first and second active agents are the same.

9. An osmotic device according to claim 8 wherein the first and second active agents are theophylline.

10. An osmotic device according to claim 1 wherein the second active agent in the external coat comprises a therapeutic agent and the first active agent in the core comprises a different therapeutic agent.

11. An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is loratadine.

12. An osmotic device according to claim 10 wherein the first active agent is ranitidine and the second active agent is a combination of ranitidine and cispripide.

13. An osmotic device according to claim 10 wherein the first active agent is pseudoephedrine and the second active agent is astemizole.

14. An osmotic device according to claim 10 wherein the first active agent is diltiazem and the second active agent is enalapril.

15. An osmotic device according to claim 1, wherein the one or more environments of use comprises a first environment of use and a different second environment of use.

16. An osmotic device according to claim 15, wherein the first environment of use is the gastric region and the second environment of use is farther down the gastrointestinal tract of a mammal.

17. An osmotic device according to claim 1, wherein the first and second active agents are released into the same environment of use.

18. An osmotic device according to claim 1, wherein the controlled delivery of one or more active agents includes one or more of pH-dependent, pH-independent, diffusion controlled, dissolution controlled, pseudo-zero order, zero-order, pseudo-first order, first-order, second-order, rapid, slow, delayed, timed, and sustained delivery.

19. An osmotic device according to claim 1, wherein at least a portion of the polymer coat dissolves or erodes in fluid present in an environment of use after the external coat has at least partially dissolved in an environment of use.

20. An osmotic device according to claim 1, wherein the polymer coat is one or more of soluble in the same environment of use in which the external coat is soluble, and soluble in the same environment of use in which the core is soluble.

21. An osmotic device according to claim 1, wherein the semipermeable membrane comprises a plasticizer and one or more of a cellulose ether, cellulose ester and cellulose-ester-ether.

22. An osmotic device according to claim 1, wherein the external coat further comprises poly(vinylpyrrolidone).

23. An osmotic device according to claim 1, wherein the polymer coat further comprises one or more of talc and poly(ethylene glycol).

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(Added new claims 24-49)

10000477-1200304

Second active agent

Sub 1